

EXHIBIT

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ETHICON, INC.

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SOMERVILLE, NEW JERSEY 08876-0151

November 12, 1987

Distribution

Mr. D. Burkley
Dr. A. Melveger
Dr. J. McDivitt
Mr. F. Schiller
Mr. R. Vetrlein

cc: Dr. A. Levy
Mr. R. Lilienfeld
Dr. B. Schwartz
RDCF

PROLENE* EXPLANTS STUDY MEETING MINUTES 10/8/87

A brief meeting was held to discuss the status of the study on PROLENE* explants received from Dr. R. Guidoin. The PROLENE samples were derived from suture materials which were used to secure human vascular grafts. The specimens were retrieved from the washed and dried specimens from the laboratory of Dr. R. Guidoin.

1. SEM work on the dried explants was completed. No cracking was found in samples which were explanted after 4.5 years (SEM and optical microscopy). One sample with 6 years of residence time showed cracking while another did not. Explants with 7-9 years of residence time showed cracking.

The next step is to do ESCA and some microscopy work to study the depth profiles of the cracks. Mr. Schiller also suggested some critical drying experiments to see if the drying procedure plays a significant role in cracking.

Mr. Schiller is in the process of issuing a report on the microscopy work completed so far.

2. Mr. Burkley examined 2 and 8 year samples by IR spectroscopy. (Memo by D. Burkley written on September 30, 1987.)

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No proteinaceous material could be detected on either of the samples indicating that the cleaning procedure used for these explants was adequate.

The surface of the 8 year sample could be easily scraped off. The material scraped from the cracked surface regions of the 8 year sample showed IR bands indicative of oxidation. The same material exhibited a melting range of 147-156°C which had been earlier assigned to oxidatively degraded polypropylene.

Microscopic examination reaffirmed that degradation occurred only on the surface of the suture and constitutes a minor portion of the suture in terms of its diameter.

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Mr. Burkley is planning to look at the remaining dry explants by IR. He will also try to see the relationship between the amount of stabilizers added to the polymer and degradation and cracking.

3. Tensile measurements on small control specimens resulted in frequent jaw-breaks. Dr. Schwartz's group will be consulted for testing small samples on the Instron. The availability of an Instron in our department in the near future will facilitate this work. A carbonate treatment on a control PROLENE sample led to slight decrease in tensile strength and a small increase in its elongation. This fact would be taken into account when interpreting mechanical properties of explants which were subjected to similar bicarbonate cleanup treatment for the removal of proteinaceous material.
4. Wet explants are being cleaned and will be subjected to similar tests as dry explants.

If there are any questions, please call.



Satya N. Garg, Ph.D.

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